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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARK A. RITCHART, J. MICHAEL STUART,
FRED H. BURBANK, and KENNETH M. GALT

Appeal 2008-5299
Application 09/734,787
Technology Center 3700

Decided:¹ March 31, 2009

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and MELANIE L.
McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a tissue sample extraction method. The Examiner has rejected the claims as

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

Claims 17-22 and 35 are pending and on appeal. We will focus on claim 17, 19-21, and 35, which read as follows:

17. A method for extracting a tissue sample from a desired site, the method comprising the steps of:

 piercing tissue with an instrument, the instrument comprising an outer hollow cannula and an inner member having a distal end portion, the inner member at least partially disposed within the hollow cannula;

 positioning the hollow cannula within the tissue at a desired tissue site;

 actuating a first mechanism associated with the instrument to move the distal end portion of the inner member distally, relative to the outer hollow cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted;

 actuating a second mechanism associated with the instrument to move the outer hollow cannula distally, relative to the distal end portion, to radially retract the distal end portion; and

 withdrawing the instrument, with the tissue sample, from the tissue.

19. The method of Claim 17 comprising grasping a tissue sample with a pair of jaws associated with the distal portion of the inner member.

20. The method of Claim 17 comprising grasping a tissue sample with a plurality of hooked extractors associated with the distal end of the inner member.

21. The method of Claim 17 wherein the step of actuating the first mechanism comprises releasing energy stored in a spring element.

35. A method for extracting a tissue sample from a desired site, the method comprising the steps of:

 providing an instrument comprising an outer hollow cannula, an inner member having a distal end portion capable of radial expansion, and at least one mechanism for moving the outer hollow cannula relative to the inner member;

piercing tissue with a distal end of the outer hollow cannula;
moving the distal end portion of the inner member from a point inside the outer hollow cannula with the at least one mechanism to a position distal of the distal end of the outer hollow cannula to expand the distal end portion of the inner member;
engaging tissue with the distal end portion of the inner member; and
moving the outer hollow cannula relative to the inner member to capture tissue within the distal end portion of the inner member.

Claims 17-19 and 35 stand rejected under 35 U.S.C. § 102(b) as anticipated by Silverman (US 2,198,319, Apr. 23, 1940) (Ans. 3).

Claim 20 stands rejected under 35 U.S.C. § 103(a) as obvious over Silverman in view of Reznik (US 4,393,872, Jul. 19, 1983) (Ans. 4).

Claims 21 and 22 stand rejected under 35 U.S.C. § 103(a) as obvious over Silverman in view of Schramm (US 5,476,101, Dec. 19, 1995) (Ans. 4).

ANTICIPATION

The Examiner finds:

Silverman discloses a method including piercing tissue with an instrument comprising an outer hollow cannula (10) and an inner member (14) having a distal end portion disposed within the hollow cannula; positioning the hollow cannula within the tissue at a desired tissue site . . . ; actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally . . . , relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted . . . ; actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion . . . ; and withdrawing the instrument and tissue sample from the tissue.

(Ans. 3.)

Issues

Did the Examiner err in concluding that Silverman discloses actuating first and second mechanisms?

Did the Examiner err in concluding that Silverman discloses grasping tissue with a pair of jaws?

Findings of Fact

1. Silverman discloses a biopsy instrument “including a hypodermic needle **10** having . . . the usual needle hub **12**” (Silverman, col. 1, ll. 34-38).
2. Silverman also discloses that “[r]otatably and slidably mounted within the customary passage **13** of the needle **10** is an interior needle having . . . an operating hub **15**” (*id.* at col. 1, ll. 39-43).
3. In addition, Silverman discloses that the “inner end of the interior needle is split for a goodly portion of its length . . . , the two portions thus formed having divergently pointed and beveled inner extremities **17**” (*id.* at col. 1, ll. 43-48).
4. Silverman discloses that, in operation, the physician plunges the needle **10** into the suspected portion [of the human body] until it reaches, for example, the tumor **20**. The next step is the insertion of the interior needle into the tumor itself in the manner indicated in dotted lines in Figure 1. This action causes the points **17**, by reason of their beveled extremities, the bevels extending in opposite directions, to be spread apart, thus assuring the inclusion of a specimen of the tumor and the holding of such specimen therebetween. The next step is the further insertion of the needle **10** to a point where it encloses the interior needle. This action causes the split portions of the interior needle to be compressed together, thus firmly enclosing the desired specimen. Both outer and inner needles are then

rotated together, thereby cutting away the lower end of the specimen. The needles are then withdrawn as a unit and the specimen **21** may be examined at will.

(*Id.* at col. 1, l. 56, to col. 2, l. 24.)

Principles of Law

“It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification.” *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Analysis

Silverman discloses a biopsy instrument “including a hypodermic needle **10** having . . . the usual needle hub **12**” and an “an interior needle having . . . an operating hub **15**” (Findings of Fact (FF) 1-2). We agree with the Examiner that operating hub 15 and needle hub 12 can be considered first and second mechanisms (Ans. 3).

Silverman also discloses inserting “the interior needle into the tumor itself in the manner indicated in dotted lines in Figure 1” and that this “action causes the points **17** . . . to be spread apart, thus assuring the inclusion of a specimen of the tumor and the holding of such specimen therebetween” (FF 4). We agree with the Examiner that this discloses “actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally . . . , relative to the outer

cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted” (Ans. 3).

In addition, Silverman discloses that the “next step is the further insertion of the needle **10** to a point where it encloses the interior needle” (FF 4). We agree with the Examiner that this discloses “actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion” (Ans. 3).

With regard to claim 17, Appellants argue that it is a mischaracterization to consider elements 15 and 12 to be the first and second mechanisms (App. Br. 5-6). In particular, Appellants argue that, “at most, Silverman may viewed as disclosing manual hand operation of the device of Silverman by hand manipulation of the operating hub 15 or needle hub [12]. . . . [S]uch operation is not properly construed as actuation of a first mechanism, nor actuation of a second mechanism.” (*Id.* at 6.)

We do not agree. “It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification.” *In re Sneed*, 710 F.2d at 1548. Giving claim 17 its broadest reasonable interpretation, we agree with the Examiner that hubs are mechanisms and that the manual movement of these hubs constitutes actuating the mechanisms (Ans. 5).

With regard to claim 35, Appellants argue that “Silverman does not teach . . . at least one mechanism for moving the needle 10 of Silverman relative to the inner needle of Silverman. Nor does Silverman teach moving the distal end portion of the inner needle of Silverman with such a

mechanism” (App. Br. 7). We are not persuaded by this argument for the reasons discussed above.

With regard to claim 19, Appellants argue that the “disclosure of a split needle of Silverman does not teach or suggest grasping tissue with a pair of jaws. . . . Instead, Silverman teaches divergently pointed needle portions.” (App. Br. 8.)

We do not agree. Silverman discloses that the “insertion of the needle **10** to a point where it encloses the interior needle . . . causes the split portions of the interior needle to be compressed together, thus firmly enclosing the desired specimen” (FF 4). Thus, we agree with the Examiner that Silverman discloses grasping tissue with a pair of jaws (Ans. 5-6).

Conclusion

Silverman discloses actuating first and second mechanisms and grasping tissue with a pair of jaws. Therefore, we affirm the anticipation rejection of claims 17, 19, and 35. Claim 18 has not been argued separately and therefore falls with claim 17. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS – CLAIM 20

The Examiner relies on Silverman for disclosing “grasping a tissue sample” (Ans. 4). The Examiner relies on Reznik for teaching “the use of a plurality of hooked extractors (16) to grasp a tissue sample” (*id.*). The Examiner concludes that it would have been obvious “to replace the grasping members as disclosed by Silverman with the hooked extractors as taught by Reznik et al. to enable the physician to more readily grasp or grip the target tissue” (*id.*).

Issue

Did the Examiner err in concluding that it would have been obvious to replace Silverman's split needle with Reznik's prongs?

Findings of Fact

5. Reznik discloses a surgical instrument that "allows continuous aspiration of a surgical site while simultaneously grasping tissue or objects" (Reznik, col. 1, ll. 47-50).

6. In particular, Reznik discloses an instrument having a tubular body and a "plurality of springy prongs [that] are integrally formed from one end of the tube and may be substantially retracted within the tubular body. The prongs upon being extended outwardly from the mouth of the body diverge; upon retraction, the prongs converge enabling objects to be captivated." (*Id.* at col. 1, ll. 49-57.)

7. Reznik discloses prongs 16 "having inwardly bent distal ends which are blunt" (*id.* at col. 2, ll. 61-63).

8. Reznik discloses that the "inwardly turned ends of prongs **16a-16d** . . . enable [sic, enable] the physician to more readily grasp or grip tissue and capture objects therebetween" (*id.* at col. 3, ll. 1-4).

Principles of Law

"[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727, 1742 (2007). However, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion to make

the proposed modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

Analysis

Silverman discloses a biopsy instrument having an inner needle that has been “split for a goodly portion of its length” (FF 1-3). Silverman also discloses that the split needle is inserted into the tumor and that this “action causes the points 17, by reason of their beveled extremities, . . . to be spread apart” (FF 4).

In contrast, Reznik discloses a surgical instrument for grasping tissue comprising a plurality of springy prongs having inwardly bent distal ends (FF 5-7). Reznik does not disclose that these prongs are inserted *into* tissue or that the action of inserting these prongs into tissue would cause the prongs to spread apart. Thus, although we agree with the Examiner that Reznik’s inwardly bent distal ends would aid in grasping tissue (FF 8), we agree with Appellants that the Examiner has not set forth a prima facie case that these prongs would be satisfactory for the intended purpose of Silverman’s split needle (App. Br. 9). Thus, we agree with Appellants that the Examiner has not set forth a prima facie case that it would have been obvious to replace Silverman’s split needle with Reznik’s prongs.

Conclusion

The Examiner erred in concluding that it would have been obvious to replace Silverman’s split needle with Reznik’s prongs. We therefore reverse the rejection of claim 20.

OBVIOUSNESS – CLAIMS 21 & 22

The Examiner finds that “Silverman discloses manually actuating the first and second mechanisms” (Ans. 4). The Examiner relies on Schramm for teaching “a biopsy apparatus having a first (55) and second (56) spring element to store energy to drive an inner and outer cannula” (*id.*). The Examiner concludes that it would have been obvious “to modify the device as disclosed by Silverman to include a first and second spring element to store energy to drive the outer hollow cannula and the inner member to allow for a more precise automated sampling procedure” (*id.*). The Examiner also argues that “the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art” (*id.*)

Issue

Did the Examiner err in concluding that it would have been obvious, based on the disclosure in Schramm, to modify Silverman’s method such that the actuating steps comprise releasing energy stored in a spring element?

Findings of Fact

9. Schramm discloses an apparatus for handling and operating a two-needle biopsy system, the first needle being received by the hollow shaft of the second needle (Schramm, Abstract & col. 11, ll. 46-64).

10. In particular, Schramm discloses an apparatus comprising a first biasing means “for biasing the first transport means, and, in turn, the first needle forwardly toward the first transport means forward position” and a second biasing means “for biasing the second transport means, and, in turn,

the second needle forwardly toward the second transport means forward position” (*id.* at col. 6, ll. 9-16).

11. Specifically, Schramm discloses that the “first and second needles are provided with first and second handles, respectively, which are fitted into first and second yokes of the apparatus” (*id.* at Abstract).

12. Schramm also discloses that “[y]okes **46** and **47** are each biased forwardly . . . by coil springs **55** and **56**, respectively” (*id.* at col. 9, ll. 60-62).

Principles of Law

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.

In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

Analysis

Silverman discloses a biopsy instrument comprising a needle 10 having needle hub 12 and an interior needle having operating hub 15, the interior needle being “[r]otatably and slidably mounted within . . . needle **10**” (FF 1-2). Schramm discloses an apparatus for handling and operating a two-needle biopsy system, comprising coil springs for biasing forward the first and second needles (FF 9-12). We agree with the Examiner that it would have been *prima facie* obvious to modify Silverman’s device to

include coil springs for biasing forward the first and second needles in order “to allow for a more precise automated sampling procedure” (Ans. 4).

Appellants argue that “the Examiner has merely picked various portions from two different prior art references, without regard to teachings in Schramm et al. that would teach away from such a combination” (App. Br. 10). In particular, Appellants argue that Schramm “states that first needle 86 is a substantially solid shaft 87 with a tissue holding region 90 cut-out from shaft 87,” that “the substantially solid shaft 87 of Schramm . . . does not teach or suggest expansion, and that one would not be motivated to make the substantially solid shaft of Schramm et al. expandable” (*id.*). In addition, Appellants argue that Schramm does not “teach or suggest an inner member having a distal end portion that is closed radially by relative movement of the inner member and the outer member” (*id.*).

Appellants also argue that Schramm “seems to teach away from the invention as claimed, because Schramm . . . teaches that the inner needle is exposed at all times” (*id.*). In particular, Appellants argue:

Because Schramm . . . teaches an inner needle with a point that is exposed during operation, it is respectfully urged that one would not be motivated to combine Schramm . . . with Silverman in the manner suggested by the Examiner. Instead, it . . . is respectfully urged that the Examiner has improperly relied on the Applicants’ teachings in hindsight in an effort to modify Silverman with the teaching’s [sic, teachings] of Schramm et al. when Schramm et al. teaches away from the needle configuration sought by Silverman.

(*Id.* at 11.)

In addition, Appellants argue:

[I]t is not clear how the resulting combination would operate to provide the claimed method. For instance, as noted above, Schramm et al.'s apparatus is configured to have the distal point of the inner needle exposed at substantially all times of operation. So if one did take the spring device of Schramm et al. and place it in Silverman, it is respectfully urged that even if the resulting combination did operate, the resulting device could (depending on how configured) leave the inner needle of Silverman substantially always exposed. In other words, even if one combined the references, it is not clear how the resulting combination would teach the claimed method.

(Id.)

We are not persuaded. The Examiner does not argue that Schramm's device should be modified to make its inner needle expandable. In addition, the Examiner is not arguing that the configuration of Silverman's needles should be modified based on the disclosure in Schramm. Instead, the Examiner is relying on Schramm to disclose the use of first and second springs to bias needles forward (Ans. 7).

We agree with Appellants that the configuration of Schramm's inner and outer needles is different from the configuration of Silverman's device. However, Appellants have not pointed to any teaching in Schramm that Silverman's configuration, if modified as posited by the Examiner, could not be effectively used for the purposes set forth in Silverman. Thus, we do not agree that Schramm teaches away from Silverman's device, or from modifying Silverman's device to include coil springs to bias the needles forward.

Conclusion

Appellants have not shown that the Examiner erred in concluding that it would have been obvious, based on the disclosure in Schramm, to modify

Silverman's method such that the actuating steps comprise releasing energy stored in a spring element. We therefore affirm the rejection of claims 21 and 22.

ORDER

We affirm the anticipation rejection of claims 17-19 and 35 and the obviousness rejection of claims 21 and 22. However, we reverse the obviousness rejection of claim 20.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

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